IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CELSIS IN VITRO, INC. a Maryland Corporation, *Plaintiff,* v. CELLZDIRECT, INC., a Delaware Corporation and wholly-owned subsidiary of INVITROGEN CORPORATION; and INVITROGEN CORPORATION, a Delaware Corporation. *Defendants.*	)	Case No. 10-cv-4053 Judge Milton I. Shadur Magistrate Judge Martin C. Ashman

MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Celsis IVT is a leading innovator in the field of cryopreserved hepatocyte products and received U.S. Patent No. 7,604,929 in October 2009. This patent discloses an innovative method for creating multi-cryopreserved human and animal hepatocytes (a type of liver cell) for use in drug discovery. Celsis IVT produces its LiverPool™ products under its '929 patent.

Unfortunately, Celsis IVT's patented technologies are being brazenly copied by would-be competitors. Yet, Celsis IVT is a relatively small company and unprepared to simultaneously manage multiple patent litigations. So, after the first '929 patent lawsuit was resolved last month with the accused product being removed from the market,[1] Celsis IVT turned to investigate CellzDirect's pooled hepatocyte products. Celsis has now confirmed that the method that must be used by CellzDirect to make its hepatocyte products infringes the '929 patent.[2]

CellzDirect's infringement is irreparably harming Celsis IVT and the need for immediate injunctive relief is critical. On the heels of the first '929 patent lawsuit, CellzDirect apparently

[1] *Celsis In Vitro, Inc. v. XenoTech, LLC, et al.*, Case No. 10-cv-0681 (N.D. Ill.) (Coar, J.).
[2] *See* Declaration of Stephen C. Strom ("Strom Decl.").

began dumping its infringing products with "buy 2 get 1 free" specials. CellzDirect's aggressive pricing forced Celsis IVT to deeply—and uncharacteristically—discount its patent-protected LiverPool™ products just this week. Aside from the repeated, detrimental effects of price erosion, Celsis IVT is also losing sales, business opportunities, and goodwill attributable to a market leader in a growth market. CellzDirect will also be promoting its infringing products head-to-head with Celsis IVT LiverPool™ products at several quickly approaching industry conferences and workshops, thereby further damaging Celsis IVT's reputation and exclusive leadership position.

CellzDirect will not stop its efforts to drive out the LiverPool™ products and apparently aspires to control the multi-cryopreserved hepatocyte market by leveraging the vast resources of its corporate parent, Invitrogen. These collective harms are very difficult to measure, if not impossible, and thus are irreparable.

I. SUMMARY OF THE ARGUMENT SUPPORTING AN INJUNCTION

This Court should enjoin CellzDirect because:

- **Celsis IVT Is Likely to Prevail On the Merits**: The '929 patent is presumed valid and will likely withstand any challenge to validity. As provided in the claim interpretation and comparison charts,[3] a person of ordinary skill in the art would know that the process CellzDirect uses to produce its multi-cryopreserved hepatocyte products infringes at least the representative claims 1 and 10 of the '929 patent.

- **Celsis IVT Is Irreparably Harmed by CellzDirect's Infringement**: As direct competitors in the relatively small field of cryopreserved hepatocyte products, Celsis IVT has suffered and continues to suffer damaging price erosion of its growth-positioned LiverPool™ products, lost sales, and significant lost business opportunities with its customers. CellzDirect's promotion of its infringing products at quickly approaching industry conferences will continue to significantly damage Celsis IVT's reputation and leadership market position. This collective harm is very difficult, if not impossible to measure.

- **The Balance of Hardships Weighs in Celsis IVT's Favor**: Celsis IVT faces continued irreparable injury if this Court does not stop CellzDirect's infringement. On balance, if an injunction issues the only "hardship" that CellzDirect faces is the inability to continue its willful infringement of the '929 patent.

[3] Strom Decl. at Exhibits D and E.

- **Granting an Injunction Is In the Public's Interest**: Public policy favors the strong enforcement of patent rights. Conversely, there is no countervailing public interest in allowing CellzDirect to continue willfully infringing the '929 patent.

II. STATEMENT OF FACTS

A. Celsis IVT Emerges as Industry Leader in Cryopreserved Hepatocyte Technologies

In 1990, Dr. Paul Silber founded In Vitro Technologies, Inc. ("IVT"), the predecessor of Celsis IVT,[4] to provide *in vitro* testing services for cosmetic companies, and by the mid 1990's, IVT was providing similar services to chemical and pharmaceutical companies.[5] Throughout the 1990's, IVT continued to grow and service more pharmaceutical customers,[6] but as customer needs shifted, IVT began selling human-based *in vitro* testing products, such as human liver microsomes[7] and animal liver microsomes to customers for their internal use in *in vitro* testing.[8] Of the two main markets for the sale of liver-based *in vitro* products (*i.e.*, toxicology and drug metabolism), only the drug metabolism market could utilize non-living cell fractions.[9]

Recognizing this early problem, IVT endeavored to provide customers with live hepatocyte cell testing or the live cells themselves.[10] But, IVT faced several hurdles because hepatocytes were difficult to isolate and had to be utilized right after isolation. To overcome these problems, IVT worked diligently to optimize its hepatocyte preservation techniques and then emerged as the industry leader in cryopreserved hepatocytes.

Though customer use of cryopreserved hepatocytes in *in vitro* testing was still expanding, IVT recognized that the then-current cryopreservation methods could not produce useful multi-

[4] In July 2006, Celsis Holdings, Inc. acquired IVT. *See* Declaration of Judy Madden ("Madden Decl.") at ¶5.
[5] Declaration of Daniel Dryden ("Dryden Decl.") at ¶¶2-3.
[6] Dryden Decl. at ¶4.
[7] Microsomes, which are liver cell fraction in vitro models, are not live cells, and therefore, are not ideal models for all in vitro testing. Dryden Decl. at ¶5.
[8] Dryden Decl. at ¶¶4-5.
[9] Dryden Decl. at ¶5.
[10] Dryden Decl. at ¶¶5-6.

donor hepatocyte pools.[11] At that time, researchers widely believed that re-cryopreservation of hepatocytes—necessary for multi-donor pools—would cause significant damage to the cells. But, multi-donor pools were desired by researchers, because having a variety of cells (*i.e.*, male, female, old, young, healthy, unhealthy) would help eliminate the effects of outlier data in research results.

This lack of multi-donor pools was compounded when working with human liver cells, because unlike research animal liver cells—which are abundant and available at any time for use by a researcher—there were scarce opportunities to obtain multiple human liver cells simultaneously and then mix them together with other human liver cells due to a lack of supply of human liver cells, the fragility of those cells, and the short harvesting time.[12] Thus, even if two human livers became available within a single day, there still would not be enough time to create a multi-donor pool. And even if a two-donor pool would work, a sample of only two different liver cells was not diverse enough to eliminate the effects of outlier data.

Recognizing these limitations, IVT scientists, Daniel Dryden and James Hardy, sought to create multi-donor hepatocyte pools that were strong enough to survive the effects of multiple cryopreservation steps.[13] Using their experience and ingenuity, Dryden and Hardy developed a novel process for producing a multi-donor hepatocyte product using, in general, the steps of cryopreserving individual sources, thawing them, forming a pool, removing non-viable cells and debris, and then re-cryopreserving the hepatocytes for storage and then their later use. IVT named this novel process the LiverPool™ method, and the resulting multi-donor hepatocyte product the LiverPool™ product. IVT filed patent applications on this new technology, which matured into the '929 patent in October 2009.

B. The LiverPool™ Products Produced By the Methods in the '929 Patent

[11] Dryden Decl. at ¶¶7-8.
[12] Dryden Decl. at ¶9.
[13] Dryden Decl. at ¶10.

Celsis IVT considers the LiverPool™ products to be its flagship products and uses these products to parlay the sales of its other products.[14] The LiverPool™ products are available as 5-, 10-, 20-, and 50-donor mixed gender pools, as well as 10-donor male only and 10-donor female only pools. Celsis IVT also offers the LiverPool™ products as custom-blended pools based on customer specific requirements.

The LiverPool™ products provide researchers several advantages, including reducing the number of wasted cells per use and minimizing the variability from study-to-study, day-to-day, and from lab-to-lab—both of which save the customer time and money.[15] The LiverPool™ products also exhibit consistent activity, cell yield from vial-to-vial, and high viability.

To support the LiverPool™ products, Celsis IVT has invested tens of thousands of dollars in equipment, materials, and resources, devoted hundreds of man hours, expended thousands of dollars in patent protection, and employed numerous science, sales, and marketing personnel.[16]

C. CellzDirect Develops Cryopreserved Hepatocyte Products Using Celsis IVT's Technologies

In 2006 CellzDirect engaged Advanced Pharmaceutical Sciences, Inc. ("APS") to exclusively produce, *inter alia*, its human multi-cryopreserved human hepatocyte products.[17] Defendant Invitrogen markets and sells these same products for CellzDirect.

The process that CellzDirect uses to produce its multi-cryopreserved hepatocyte products involves the steps of cryopreserving individual donor lots, thawing these lots, pooling them, and then re-cryopreserving them for later use.[18] For example, CellzDirect's HuP58 product, a human 10-donor pool (5 male; 5 female), is a pre-pooled twice-cryopreserved hepatocyte product that was produced using a process performed by APS. HuP58 exhibits initial viabilities of 81% and 71%, respectively, and a particular metabolic profile when tested for certain enzymatic activities.

[14] Madden Decl. at ¶6.
[15] Dryden Decl. at ¶¶13-14, 15.
[16] Dryden Decl. at ¶12.
[17] Strom Decl. at ¶36.
[18] Strom Decl. at ¶37.

HuP58 is useful in *in vitro* drug metabolism studies, such that the results of a single assay would represent the average of multiple individuals.

D. CellzDirect Has Recklessly and Unnecessarily Provoked This Motion

Since March 2008, CellzDirect has known about Celsis IVT's invention when Celsis IVT provided CellzDirect with written notice of the published patent application that eventually ripened into the '929 patent.[19] CellzDirect has also known that this published patent application covered Celsis IVT's Liverpool™ products.[20] Yet, CellzDirect has continued to actively use, market, and sell its infringing products in direct competition with Celsis IVT's Liverpool™ products.[21] Moreover, CellzDirect has been engaging in a price-dumping strategy aimed at flooding the market with its infringing products likely intended to drive out the LiverPool™ products and its discounting efforts are accelerating.[22] Given the significant financial resources of Invitrogen, CellzDirect will continue this excessive discounting strategy for its infringing products until it drives Celsis IVT out of business. Alternatively, CellzDirect may realize that its infringing days are numbered, so it is trying to shed as much inventory as possible before this lawsuit. Whatever its motives are, if these tactics continue, CellzDirect will single-handedly cripple the pooled cryopreserved hepatocyte market and perhaps force Celsis IVT out of the business it invented.

E. CellzDirect's Attendance at Upcoming Industry Conferences Will Tarnish Celsis IVT's Reputation and Erode Its Market Share

The cryopreserved hepatocyte market, which includes the sales of pooled and single-donor cryopreserved hepatocytes, is comprised of only a small number of companies whose reputations are built, in part, by the quality of their products, services, and innovative contributions in the field of drug development.[23] Important venues to establish and build a company's reputation are

[19] Dkt. # 1, Complaint ¶¶7-9, 23-25.
[20] Dkt. # 1, Complaint ¶¶23-25.
[21] Dkt. # 1, Complaint ¶28.
[22] Supplemental Madden Declaration ("Supp. Madden Decl.") at ¶¶1, 3.
[23] Madden Decl. at ¶30.

the many regional, national, and international conferences that occur throughout the year.[24] For Celsis IVT these conferences are critical venues for building its reputation with its customers.

There are several upcoming professional conferences where the parties will be presenting and marketing their respective pooled cryopreserved hepatocyte products head-to-head.[25] Celsis IVT will be marketing its LiverPool™ products against CellzDirect's copycat, cheaper pooled cryopreserved hepatocyte products, which will continue to affect the sales and leadership position of Celsis IVT. In addition to conferences, companies within this industry, including Celsis IVT and CellzDirect, conduct workshops for their customers and potential customers.[26] These workshops are valuable opportunities for companies to extend their scientific credibility by demonstrating their products in an informal, one-on-one setting, and thus are also critical venues for establishing and solidifying customer relationships and future revenue streams.

III. A PRELIMINARY INJUNCTION AGAINST CELLZDIRECT IS APPROPRIATE

A. The Preliminary Injunction Standard in Patent Cases

The Patent Act vests the Court with broad discretion to enjoin infringement of Celsis IVT's '929 patent. *See* 35 U.S.C. § 283. Celsis IVT is entitled to a preliminary injunction because it can establish (1) a reasonable likelihood of its success on the merits that CellzDirect's multi-donor pooled cryopreserved hepatocyte products infringe the '929 patent; (2) that Celsis IVT will continue to suffer irreparable harm if injunctive relief is denied; (3) that the harm Celsis IVT will suffer if preliminary relief is denied far outweighs the harm that CellzDirect will suffer if relief is granted; and (4) the public's interest in entering a preliminary injunction and enforcing Celsis IVT's patent rights. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008). When balancing these factors, the Court should apply a "sliding scale" approach: the more likely

[24] Madden Decl. at ¶31.
[25] Madden Decl. at ¶32.
[26] Madden Decl. at ¶34.

Celsis IVT is to win, the less the balance of harm needs to favor Celsis IVT. *Ty, Inc. v. Jones Group, Inc.*, 237 F.3d 891, 895 (7th Cir. 2001).

B. CELSIS IVT IS HIGHLY LIKELY TO PREVAIL ON THE ISSUE OF INFRINGEMENT OF THE '929 PATENT

1. The Evidence Establishes that the '929 Patent is Valid and Infringed by CellzDirect

To establish a likelihood of success on the merits, Celsis IVT need only demonstrate a "reasonable probability" of prevailing on its claim for patent infringement. *See H.H. Robertson Co. v. United Steel Deck*, 820 F.2d 384, 390 (Fed. Cir. 1987). To prevail on its infringement claim, Celsis IVT must show (1) ownership[27] of a valid patent, and (2) that CellzDirect infringes that patent. *See* 35 U.S.C. § 271. Here, Celsis IVT will likely prevail on the merits, because it proves below that the process CellzDirect uses to make its cryopreserved hepatocyte products and to perform its *in vitro* testing services using these products infringes the '929 patent.

a. The '929 Patent is Valid

Under 35 U.S.C. § 282, the '929 patent "is presumed valid . . . at every stage of the litigation." *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). Only if "a party opposing a request for a preliminary injunction raises a 'substantial question' concerning the validity of the patent," must the party seeking injunctive relief establish that the invalidity defense lacks merit. *New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 883 (Fed. Cir. 1992). Thus, if an infringer, like CellzDirect, is unable to "identify any persuasive evidence of invalidity, the very existence of the patent satisfies the patentee's burden on the validity issue." *Canon Computer Sys.*, 134 F.3d at 1088.

Notwithstanding Celsis IVT's right to the presumption of validity, we present evidence that none of the prior art references cited on the face of the '929 patent alone or collectively

[27] Assignment Records of the US Patent Office at 96981/661 prove Celsis IVT owns the '929 patent.

teach the invention.[28] Moreover, the validity of the '929 patent is demonstrated by Celsis IVT's substantial sales, CellzDirect's copying, and other factors inconsistent with invalidity.

b. The CellzDirect Products Are Made by a Process That Infringes the '929 Patent

To determine a likelihood of infringement, the Court must (1) first determine, as a matter of law, the correct meaning and scope of the asserted claims, and then (2) compare the properly construed claims to the accuse process. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995). A patent is infringed if any single claim is infringed, *see TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1379 (Fed. Cir. 2008) ("Under the 'all elements' rule, to find infringement, the accused device must contain 'each limitation of the claim, either literally or by an equivalent.'"), so Celsis IVT does not need to show that CellzDirect infringed every claim of the '929 patent. Rather, for purpose of this motion and to avoid any unnecessary burden on the Court, Celsis IVT analyzes only certain representative claims, including Claims 1 and 10 of the '929 patent. Applying the Federal Circuit's two-step analysis, the process CellzDirect uses to make its cryopreserved hepatocyte products meets each of the properly construed elements of claims 1 and 10 of the '929 patent.

1. Construing the Claims of the '929 Patent

Claim construction begins with the claim itself. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The Court must first ascertain the plain and ordinary meaning of the term in the claim. *Id*. The plain and ordinary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art at the time of the invention. *Id*. "Importantly, the person of skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id*.

[28] Strom Decl. at ¶¶106-107.

Here, Celsis IVT has provided the Court with the evidence necessary to construe the exemplar claims 1 and 10 of the '929 patent from the perspective of one of ordinary skill in the art. In particular, that evidence can be found with the Declaration of Dr. Stephen C. Strom,[29] an expert in hepatocyte-related technologies such as those disclosed in the '929 patent. Dr. Strom is familiar with people of ordinary skill in the art at the time of the invention of the '929 patent. In his Declaration, Dr. Strom provides a claim construction chart[30] detailing his opinion of how a person of ordinary skill in the art at the time of the invention would have interpreted various claim terms appearing in the '929 patent based on the claim terms' plain and ordinary meanings, the claims themselves, the specification, and the prosecution history, as follows:

- "*preparation of multi-cryopreserved hepatocytes*" means a composition of hepatocytes that have been frozen and thawed at least two times according to the claimed process.
- "*density gradient fractionation*" means a process for separating viable hepatocytes from non-viable hepatocytes based on their density.
- "*without requiring a density gradient fractionation step after thawing the hepatocytes for a second time*" means that the claimed process does not require a density gradient fractionation step after thawing the hepatocytes a second time.
- "*plated*" means to have placed hepatocytes on a laboratory plate containing attachment substrates.
- "*the hepatocytes of said preparation are viable after the final thaw*" means the percentage of living hepatocytes relative to the total cell population in the preparation, when determined after the final thaw.
- "*incubating*" means simulating certain biological conditions.
- "*xenobiotic*" means a substance foreign to the body.
- "*metabolic fate*" means the modification of the chemical structure or the localization of the xenobiotic by the hepatocytes.

Based on the evidence provided by Celsis IVT (including the patent and its file history), the Court may properly construe the scope of Claims 1 and 10 the '929 patent.

2. Applying the Construed Claims 1 and 10 of the '929 Patent to the CellzDirect Process Used to Make Its Infringing Products

Next, after construing the claims, the Court must apply Claims 1 and 10 of the '929 patent to the process CellzDirect uses to make its infringing products. *Markman*, 52 F.3d at 970-

[29] *See generally* Strom Decl.
[30] Strom Decl. at Exhibit D.

71. To aid the Court in analyzing representative Claims 1 and 10 of the '929 patent, Celsis IVT has provided the Court with a claim comparison chart,[31] which establishes element-by-element that the process CellzDirect uses to make its cryopreserved hepatocyte products infringes at least the two representative claims 1 and 10 (as well as Claims 3-5 and 7) of the '929 patent. As such, Celsis IVT has demonstrated a strong likelihood of success on the merits.

C. Celsis IVT Is Being Irreparably Harmed by CellzDirect

Celsis IVT has been and continues to be irreparably harmed by CellzDirect's infringement in a number of ways that are very difficult, if not impossible, to measure. For example, since CellzDirect began selling its infringing products, Celsis IVT has experienced significant price erosion of the LiverPool™ products.[32] The latest example of this price erosion occurred just this week as a customer requested Celsis IVT to deeply discount its LiverPool™ products in order to compete with CellzDirect's offer.[33] This erosion will continue until CellzDirect's infringing products are removed from the market. Even after CellzDirect is enjoined, reversing the erosion will be a slow process, at best.

Celsis IVT has also lost several sales to customers who purchased infringing products from CellzDirect.[34] While Celsis IVT may know of a few examples of lost sales, Celsis IVT has likely lost other sales as demonstrated by CellzDirect's reduction in its published inventory of infringing products. To date, Celsis IVT has not earned back the business from these lost sales, except for in one instance where the customer came back to Celsis IVT and demanded a deep discount. Other customers have demanded smaller concessions from Celsis IVT to compete with the prices offered by CellzDirect.

While any lost sale is an unpleasant event for a company, a lost sale of a LiverPool™

[31] *See* Strom Decl. at Exhibit E.
[32] Declaration of Mark A. Peterson ("Peterson Decl.") at ¶¶6, 29.
[33] Supp. Madden Decl. at ¶2.
[34] Madden Decl. at ¶¶13-18, 20, 21-22, and 29.

product for Celsis IVT is especially damaging.[35] Customers typically purchase the LiverPool™ products only once or twice a year. And once they do, that customer may purchase additional vials from the same lot to ensure data comparability over time. So a lost sale now means that Celsis IVT may also lose the opportunity to earn future business. To earn back that lost customer, Celsis IVT would need to either offer deeper discounts than otherwise would be necessary in the absence of CellzDirect's infringement or wait until that customer is sufficiently dissatisfied with CellzDirect's products. Hence, so long as CellzDirect's infringing products remain on the market, Celsis IVT will continue to face irreparable harm.[36]

Celsis IVT sets the prices of the LiverPool™ products based upon a variety of customer-, product-, and competitor-driven factors and only discounts its LiverPool™ products for strategic business reasons.[37] Having experienced these deep discounts, customers will likely not embrace any price increases on the LiverPool™ products. Thus, the opportunity for Celsis IVT to price its LiverPool™ products at a level that reflects their real proprietary value has been seriously undermined by CellzDirect's infringement and their aggressive pricing strategy.[38]

In addition, Celsis IVT can neither predict how far the price for LiverPool™ will erode,[39] nor identify other lost opportunities to sell other products as a result of the reputation and quality of its flagship LiverPool™ products. Moreover, CellzDirect's infringement has caused a loss of goodwill and reputation attributable to a market leader in a growth market.[40] The LiverPool™ products are presently in a growth phase of their product lifecycle, as Celsis IVT continues to build the LiverPool™ brand, expand its customer base, and establish its reputation and leadership position.[41] Absent CellzDirect's infringement, the LiverPool™ products should soon be entering a more mature phase where Celsis IVT will earn its highest revenues and achieve its

[35] Madden Decl. at ¶19; Peterson Decl. at ¶¶26-28.
[36] Peterson Decl. at ¶¶26-28.
[37] Madden Decl. at ¶¶24-26, 29.
[38] Madden Decl. at ¶29; Peterson Decl. at ¶21.
[39] Madden Decl. at ¶23.
[40] Peterson Decl. at ¶30.
[41] Madden Decl. at ¶8.

strongest market position. But so long as CellzDirect's infringement continues, Celsis IVT cannot establish the highest goodwill attributable to a market leader in a growth market.[42]

Celsis IVT also relies heavily upon professional conferences and invitation-only workshops to establish and build its reputation with its customer base.[43] CellzDirect markets its infringing products at these same events, affecting the sales and leadership position of Celsis IVT.[44] CellzDirect also conducts direct workshops for its customers to promote its infringing products.[45] Since these workshops are private, Celsis IVT does not know what CellzDirect discloses about its infringing products or the LiverPool™ products, but regardless these venues could have a further negative impact to Celsis IVT's reputation and goodwill.

Celsis IVT has retained exclusive rights to the '929 patent, and has never licensed it to another competitor for a reason.[46] Celsis IVT has "manifest[ed] an interest in maintain[ing] an exclusive position in the relevant market," thereby providing further evidence that money damages would be inadequate. *See Illinois Tool Works, Inc. v. Grip-Pack, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990). By retaining exclusive rights to the '929 patent, Celsis IVT has ensured that potential copiers of its technology, such as CellzDirect, are excluded from the market. This exclusivity is further evidence in support of a finding of irreparable harm.

Lastly, CellzDirect's infringement has significantly disrupted Celsis IVT's internal personnel.[47] As a small company, Celsis IVT does not have permanent internal personnel who coordinate and manage litigation with outside counsel. As a result, Celsis IVT has had to disrupt the daily responsibilities of employees throughout the entire company and devote significant hours analyzing CellzDirect's products and otherwise assisting counsel for this suit, losing time

[42] Peterson Decl. at ¶8.
[43] Madden Decl. at ¶¶30-34.
[44] Madden Decl. at ¶32; Peterson Decl. at ¶¶23-24.
[45] Madden Decl. at ¶34.
[46] Madden Decl. at ¶7; Peterson Decl. at ¶11.
[47] Madden Decl. at ¶35.

which otherwise could have been spent contributing to the revenue-generating objectives of Celsis IVT. This lost time and significant expense cannot be recouped.

Accordingly, Celsis IVT asks this Court to find that it has been and continues to be irreparably harmed and then enjoin CellzDirect from inflicting any further damage.

D. The Balance of Hardships Between The Parties Weighs Heavily in Favor of Celsis IVT

While Celsis IVT will continue to be irreparably damaged if CellzDirect is not preliminarily enjoined from using and selling its infringing products, the only "hardship" CellzDirect faces is its inability to infringe the '929 patent. CellzDirect assumed this risk when it copied Celsis IVT's patented process, began using and selling infringing products—and then continued to do so despite being fully aware of the published patent application which issued as the '929 patent. CellzDirect cannot now complain about the effects of an injunction as a result of its deliberate and wrongful conduct. *A&E Prods. Group, Inc. v. California Supply*, 28 U.S.P.Q.2d 1041, 1048 (C.D. Cal. 1993). Besides, the harm CellzDirect faces is easily calculated, purely monetary, and protectable by a bond. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1567 (Fed. Cir. 1996). On the contrary, the harm to Celsis IVT continues to be severe and long-lasting and has many incalculable components. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Accordingly, on balance, the removal of CellzDirect's infringing products from the market place is far outweighed by the immediate and irreversible harm to Celsis IVT.

E. Granting an Injunction Here Is in The Public's Interest

Finally, the public interest weights in favor of the grant of injunctive relief in light of the "strong public policy favoring the enforcement of patent rights." *PPG*, 75 F.3d at 1567. More importantly, given Celsis IVT's likelihood of success on the merits, the public interest lies in protecting Celsis IVT's patents. *A & E Products*, 28 U.S.P.Q.2d at 1049. The Federal Circuit has explained without the power to enter injunctions for patent infringement, patents would be

valueless. *Smith International, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-78 (Fed. Cir. 1983). Thus, granting injunctive relief and enforcing Celsis IVT's right to exclude CellzDirect will protect the fruits of Celsis IVT's labor—the '929 patent. Conversely, there is no countervailing public interest in permitting CellzDirect to continue infringing the '929 patent and the public will not suffer the inability to purchase cryopreserved hepatocyte products, because Celsis IVT's Liverpool™ products and the products of its competitors will remain available.

IV. CONCLUSION

For the foregoing reasons, Celsis IVT respectfully requests that the Court grant its motion for a preliminary injunction until the Court holds a trial on the merits.

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By: /s Adam G. Kelly

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